K013560

510(k) Summary

As Required by 21 section 807.92 (c)

JAN 1 6 2002

1-Submitter Name: Semperit Technische Produkte GmbH & Co KG
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A-1031 Vienna AUSTRIA
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5-Contact Person: Dipl.-Ing. Richard Ehrenfeldner
6-Date summary prepared: October 15th, 2001
7- Official Correspondent: Mansour Consulting
8- Address: 1308 Morningside Park Dr
Alpharetta, GA 30022 USA
9- Phone: (678) 908-8180
10- Fax: (425) 795-9341
11- Contact person: Jay Mansour, president
12-Device Trade or Proprietary Name: sempermed® SUPREME
13-Device Common or usual name: Surgeon's glove
9-Device Classification Name: Surgeon's glove
10-Substantial Equivalency is claimed against the following device:
"Supreme" Sempermed® Latex Surgeon's gloves, powder-free 510k #k981096 (refer to Appendix 2 for FDA notification letter
This notification for the sempermed® SUPREME is of the ABBREVIATED type as per the declaration of conformity on page 4 of this summary.

THIS DEVICE (SUPREME) UNDERWENT A CHANGE IN MATERIALS FOR WHICH THIS NEW 510K IS NEEDED (refer to section D3 in CDRH Submission cover sheet) AS 510K #K981096 APPLIES FOR PREVIOUS DEVICE BEFORE IT INCURRED THE CHANGE IN MATERIAL

11-Description of the Device:
sempermed® SUPREME is a sterile powder-free surgeon's glove. It is a disposable device made of natural rubber inside coated with a layer of polyurethane derivatives and butadiene-based copolymer cross-linked by polyacrylates- ~~free of proteins,~~ siliconized. This glove is intended to be worn on the hands, usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants. Water soluble protein less than 50 µg/dm²

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12-Intended use of the device: *(Indications for use typed on a separate FDA form)*
sempermed® DERMA plus is a powdered surgeon's glove and it is a disposable device made of natural rubber inside coated with synthetic latex material that bears powder to facilitate donning and it is intended to be worn on the hands usually in surgical settings, to provide a barrier against potentially infectious materials and other contaminants. The glove is powdered with absorbable dusting powder USP Grade

13-Safety and effectiveness of the device:
The **sempermed® SUPREME** is safe and effective as the predicate device as only minor change in materials occurred. Indeed, it is equivalent. This is better expressed in the tabulated comparison (Paragraph 14 below)

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14-Summary comparing technological characteristics with other predicate device:

General comparison result between **sempermed® SUPREME** gloves and the predicate device (**sempermed®** SUPREME ("PREVIOUS MATERIALS") is tabulated below.

Technical comparison of specific elements is attached in the main submission

FDA file reference number	510k 981096
Attachments inside notification submission file	REFER TO APPENDIX 2
TECHNOLOGICAL CHARACTERISTICS	*Comparison result* **REFER TO ADDITIONAL TECHNICAL COMPARATIVE TABLE WITHIN 510K SUBMISSION**
Indications for use	Identical
Target population	Identical
Design	Identical
Materials	Similar
Performance	Identical
Sterility	Identical
Biocompatibility	Identical
Mechanical safety	Identical
Chemical safety	Identical
Anatomical sites	Identical
Human factors	Identical
Energy used and/or delivered	Identical (not applicable)
Compatibility with environment and other devices	Identical
Where used	Identical
Standards met	Identical
Electrical safety	Identical (not applicable)
Thermal safety	Identical (not applicable)
Radiation safety	Identical (not applicable)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 1 6 2002

Semperit Technische Produkte Gesellshaft
C/O Mr. Jay Mansour
Mansour Consulting
1308 Morningstar Park Drive
Apharetta, Georgia 30022

Re: K013560
Trade/Device Name: Sempermed Supreme Powder Free Latex Surgeon's Gloves with Protein Content Labeling Claim (50 Micrograms or Less)
Regulation Number: 878.4460
Regulation Name: Surgeon's Gloves
Regulatory Class: I
Product Code: KGO
Dated: October 15, 2001
Received: October 26, 2001

Dear Mr. Mansour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements

of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Statement

Applicant:

510(k) Number (if known): K013560

Device Name: Sempermed Supreme Powder Free Latex Surgeon's Gloves With Protein Content Labeling Claim (50 Microgram or Less)

Indications For Use:

A surgeon's glove is a device made of natural or synthetic rubber intended to be worn by operating room personnel to protect a surgical wound from contamination.
(21CFR 878.4460)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Clin S. Lim

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013560

(Optional Format 3-10-98)